

K053612

510(k) Summary
Dri-STAT® ACP Reagent

1.0 **Submitted By:**

Eri Hirumi
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Beckman Coulter, Inc.
200 S. Kraemer Blvd., W-110
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APR 26 2006

2.0 **Date Submitted:**

December 23, 2005

3.0 **Device Name(s):**

3.1 **Proprietary Names**
Dri-STAT® ACP Reagent

3.2 **Classification Name**
Acid phosphatase (total or prostatic) test system (21 CFR § 862.1020)

4.0 **Predicate Device:**

Candidate(s)	Predicate	Manufacturer	Docket Number
Dri-STAT® Reagent ACP on Synchron Systems	Dri-STAT® Reagent ACP On Cobas Fara	Beckman Coulter, Inc.*	K821674

*Beckman Coulter, Inc., Brea, CA

5.0 **Description:**

The Dri-STAT® Reagent ACP may be used on the family of Synchron Systems. The reagent kit contains 20 reagent bottles that needs to be manually transferred into a Beckman Coulter User-Define Cartridge. Also with 1 bottle of Acetate Buffer. The reagent kit contains a bottle of Acetate Buffer along with a sample treatment.

6.0 **Intended Use:**

Dri-STAT® Reagent ACP is intended for use in the in vitro diagnostic determination of total acid phosphatase and non-prostatic acid phosphatase in human serum as a User Defined Reagent (UDR) application on SYNCHRON® Systems.

7.0 **Comparison to Predicate(s):**

The following table shows similarities and differences between the predicates identified in Section 4.0 of this summary.

Similarities	
Intended Use	Same as Beckman Coulter Dri-STAT® ACP Reagent, on Cobas Fara
Methodology	
Reactive Ingredients	
Sample Types	
Shelf Life	
Reaction Type	
Differences	
Instrument Platforms	Cobas Fara (Predicate) vs. Synchron® Systems (candidate)
Reference Intervals @ 37°C	≤5.4 U/L male on predicate
Total Acid Phosphatase (TACP)	2.5-11.7 U/L male per literature
Reference Intervals @ 37°C	≤1.2 U/L male on predicate
Non-prostatic Acid Phosphatase (NPAP)	0.2 – 3.5 U/L male per literature
Wavelength	405 nm on predicate 410 nm on candidate
Analytical Range	Predicate: 0 – 38 U/L Candidate: 2 – 38 U/L
Reaction Volumes	0.20; 3.00; 0.025 mL on predicate 25; 200; 6 µL on candidate

8.0 Summary of Performance Data:

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to chemistry test systems already in commercial distribution. Equivalence is demonstrated through method comparison, linearity, and imprecision experiments.

Dri-STAT Reagent ACP Method Comparison Study Results

Candidate Method	Sample Type	Slope	Inter-cept	R	n	Predicate Method
Dri-STAT Reagent ACP On Synchron LX Systems	Serum TACP	1.093	0.143	0.994	94	Dri-STAT Reagent ACP On Cobas Fara
Dri-STAT Reagent ACP On Synchron LX Systems	Serum NPAP	1.066	-0.197	0.979	47	Dri-STAT Reagent ACP On Cobas Fara
Dri-STAT Reagent ACP On Synchron CX Systems	Serum TACP	1.075	0.460	0.997	94	Dri-STAT Reagent ACP On Cobas Fara
Dri-STAT Reagent ACP On Synchron CX Systems	Serum NPAP	1.088	-0.172	0.994	47	Dri-STAT Reagent ACP On Cobas Fara

Dri-STAT Reagent ACP Estimated Imprecision - TACP

Sample	Mean (U/L)	S.D. (U/L)	%C.V.	N
Within-Run Imprecision				
Serum Control 1	3.81	0.18	4.72	80
Serum Control 2	20.6	0.26	1.28	80
Serum Control 3	37.0	0.50	1.35	80
Human Pool	35.5	0.58	1.63	80
Total Imprecision				
Serum Control 1	3.81	0.19	4.99	80
Serum Control 2	20.6	0.35	1.70	80
Serum Control 3	37.0	0.64	1.73	80
Human Pool	35.5	0.91	2.56	80

Dri-STAT Reagent ACP Estimated Imprecision - NPAP

Sample	Mean (U/L)	S.D. (U/L)	%C.V.	N
Within-Run Imprecision				
Serum Control 1	2.60	0.21	8.08	80
Human Pool	2.96	0.24	8.11	80
Total Imprecision				
Serum Control 1	2.60	0.21	8.08	80
Human Pool	2.96	0.29	9.80	80

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Eri Hirumi
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Brea, CA 92822-8000

APR 26 2006

Re: k053612
Trade/Device Name: Dri-STAT® Reagent ACP
Regulation Number: 21 CFR§862.1020
Regulation Name: Acid Phosphatase (total or prostatic) test system
Regulatory Class: Class II
Product Code: CKB
Dated: March 22, 2006
Received: March 23, 2006

Dear Mr. Hirumi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

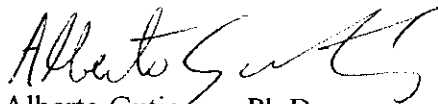
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Alberto Gutierrez", with a stylized flourish at the end.

Alberto Gutierrez, Ph.D.

Director

Division of Chemistry and Toxicology

Office of In Vitro Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K053612

Device Name: Dri-STAT[®] REAGENT ACP

Indications For Use:

Dri-STAT[®] Reagent ACP is intended for use in the in vitro diagnostic determination of total acid phosphatase and non-prostatic acid phosphatase in human serum as a User Defined Reagent (UDR) application on SYNCHRON[®] Systems.

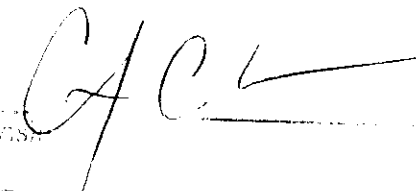
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)


Office of In Vitro Diagnostic Devices

Office of
Evaluation

Diagnostic Device
Safety

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